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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,644	CORNISH, VIRGINIA W.	
	Examiner	Art Unit	
	Hope A. Robinson	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *133, 135,-137, 141-147 and 150-160* is/are pending in the application.

4a) Of the above claim(s) *133, 135,-137, 141-147 and 150-157* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *158-160* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/25/06;5/23/05;11/10/03; 11/5/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Application Status

1. Applicant's election with traverse of Group II (claims 158-160) on July 19, 2006 is acknowledged.

2. The traversal is on the grounds that the claims are not restricted because applicant states that the claims of both Group I and II recite an improved screening method often referred to as a three-hybrid method. It is further stated that the improvement in the claims is the use of methotrexate as one of the two members of the covalent inducer of dimerization (CID) molecule employed in the three-hybrid method. Applicant concludes that the improvement is the linking feature of the pending claims. Applicant also states that there is no burden of search. Applicant's statements have been considered but are not persuasive. Claim 133 is directed to identifying a molecule that binds to a known target (said target does not have to be a protein based on the breath of the claim, a small molecule which could encompass a protein or a nucleic acid etc.). In addition, claim 133 is directed to forming a screening molecule by covalently bonding each molecule in a pool of candidate molecules to a substrate. Note that claim 158 is directed to a method of identifying a protein target, which is unknown, and binding occurs with a methotrexate or analog thereof. The objective of the claims differ and the method steps differ, thus, they are patentably distinct. MPEP chapter 800 states

that restriction requirement is proper if the inventions are independent and/or distinct.

Thus, the restriction requirement is deemed proper and is final.

3. Claims 1-132, 134, 138-140 and 148-149 have been canceled. Claim 160 has been added. Claims 133, 135,-137, 141-147 and 150-160 are pending. Claims 158-160 are under examination. Claims 133, 135,-137, 141-147 and 150-157 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Abstract

4. The Abstract is objected to because of the following informalities:

Applicant is reminded of the proper content of an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Specification

5. The specification is objected to because of the following informalities:

(a) The specification is objected to because the priority information on page 1 needs to be updated, for example, application number 09/768,479 is now abandoned.

(b) The specification is objected to because page 7 only has three lines and the rest of the page is blank.

(c) The specification is objected to because the following typographical errors appears throughout the specification, see "genomicDNA and syntheticDNA" on page 25, for example.

(d) The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following is suggested: "Methods and Assays for Screening Protein Targets".

Correction is required.

Sequence Compliance

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR1.821 through 1.825; applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicant is required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier, i.e., "SEQ ID NO:". The specification discloses sequences that have not been identified by a sequence identifier, see for example, page 23, line 11. If these sequences have not been

disclosed in the computer readable form of the sequence listing and the paper copy thereof, applicant must provide a computer readable form of the "Sequence Listing" including these sequences, a paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable form copies are the same and, where applicable, include no new matter as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). See the attached Notice to Comply with the sequence rules.

Drawing

7. The drawings filed on November 10, 2003 are objected to because Figures 15-17 re dark, thus difficult to discern the image. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the

changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objection

8. Claim 159 is objected to because of the following informalities:

Claim 159 is objected to because of the following typographical errors: "genomicDNA and syntheticDNA".

Correction is required.

Information Disclosure Statement

9. The Information Disclosure Statements filed on April 25, 2006; May 23, 2005;November 5, 2004; and November 10, 2003 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Claim Rejections - 35 USC ∋ 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 158-160 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a method for identifying a protein target comprising providing a screening molecule comprising a methotrexate moiety or an analog of methotrexate, thus the claims encompass a genus of analogs. Neither the claims nor the instant specification provides adequate description of the genus of analogs encompassed in the claims. In addition, the claimed method utilizes at least two fusion proteins and a DNA reporter gene and the claims place no structural limitation on any of these molecules. Note that the claims define these molecules functionally only. Thus, the claims encompass a large genus of any and all possible fusion protein dimerization system. Therefore, the skilled artisan cannot envision the detailed chemical structure of the genus encompassed in the claims. To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the claimed invention (for example, see *In re Edwards, 568,F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978)*.

The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately

described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In addition, the recitation of for example, "the encoding DNA is a cDNA" does not rectify the deficiency herein. Just the generic term "cDNA" did not provide an adequate written description for the broad class of mammalian or vertebrate insulin DNA in Lilly, neither does this same terminology provide adequate written description for this broad class of screening molecules (see *University of California v. Eli Lilly and Co., 43 USPQ2d1398, 1406 (1997)*). Likewise the first and second fusion proteins and reporter genes are only set forth in functional terms and there is no genetic code to correlate the structure with the function.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Furthermore, the general knowledge and level of skill in the art cannot supplement the omitted description because no known structure/function relations and/or chemical properties exist that could otherwise be used to show possession of the enormous genus. Further, *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991)*, states that "applicant must convey with

reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993).*

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

11. Claims 158-160 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabled for the Dex-Mtx dimerization system used to induce dimerization of LexA-GR and DHFR-B42 and the use of a lacZ reporter, does not reasonable provide enablement for the use of any screening molecule with any set of fusion proteins or any analogs of methotrexate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make the invention commensurate in scope with these claims. The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands, 858 F.2d at 737, 8 USPQ2d at1404 (Fed. Cir. 1988*). The factors most relevant to the instant invention are discussed below.

The amount of experimentation required to practice the claimed invention is undue as the claims encompass an unspecified amount of methotrexate analogs. In addition, the claimed method is directed to covalent binding of a ligand with specificity to the unknown protein target, which renders the claimed method as inoperable, because specificity would require a protein target that is known. Determination of a ligand with a known function that would bind to an unknown protein covalently would require undue experimentation. Further, the claimed method utilizes at least two fusion proteins and a DNA with a reporter gene, which are only described in functional terms, as no correlation is made between structure and function. The claims encompass a large genus of fusion protein dimerization system. Due to the large quantity of experimentation necessary to generate the infinite number of analogs and ligands

recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

The state of the art is unpredictable, for example, Abida et al. (ChemBioChem, 2002, vol. 3, pages 887-895) state that, "while several three-hybrid systems have been reported, little has been done to characterize these systems and understand the influence of the CID and protein-chimera structure of the transcription and infinite number of possibilities(see page 887, col. 1, paragraph 1 and page 893, last paragraph). According to Abida et al., surprisingly we find that, though both proteins are inhibited by Mtx with picomolar affinity, the transcription read-out for the two proteins differs dramatically (see page 892-893 of the reference). Abida et al. conclude that they could not explain the results obtained wherein the proteins exhibited different results, which speaks to the high level of unpredictability in the art. In addition, the claimed invention is unpredictable because the claimed method is inoperable. No indicia is provided as to the claimed analogs characteristics to be able to effect a covalent bond with a ligand that will specifically bind to a unknown protein target. The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims. The specification sets forth a single working example, which does not rectify the missing information in the instant specification pertaining to the claimed genus. The nature and properties of this claim is

difficult to ascertain from the example provided as one of skill in the art would have to engage in undue experimentation to practice the claimed invention commensurate in scope with the claims.

The specification does not provide support for the broad scope of the claims. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck, 947 F.2d 488, 496 & n.23, 20 USPQ 2d 1438, 1445 *n.23 (Fed. Cir. 1991)*. The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)*.

Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

12. Claims 158-160 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 158 and the dependent claims hereto are incomplete. Claim 158 is directed to a method for identifying a protein target having the steps of "providing a screening molecule; introducing the screening molecule into a cell; permitting the screening molecule to bind; selecting which cell expresses the reporter gene and identifying the unknown protein target. Note that the method does not include a step to isolate or recover said protein target in order to identify it, thus the claim is incomplete. In addition, it is unclear in item (a) whether the "methotrexate moiety" is also covalently bonded to a ligand or just the "analog of methotrexate". Note that item (d) is confusing for the recitation of "selecting which cell expresses the reporter gene" in view of item (b) which recites introducing the screening molecule into a cell...and a reporter gene wherein expression of the reporter gene is conditioned on the proximity of the first fusion protein to the second fusion protein, because, it appears that cell selection already took place in item b. It is unclear whether the method step is intended to be an isolation step. Claim 158 is indefinite for the recitation of "a ligand which has a specificity for an unknown protein target" because if the protein is unknown, how will the ligand have specificity to it or a particular ligand selected for binding.

Claim 160 is indefinite, in view of the fact that claim 158 recites an unknown protein, it is unclear what ligand would be selected that specifically binds said protein and for said ligand to possess a known activity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 158-160 rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (J. Am. Chem. Soc., 2000; Cited on IDS).

Lin et al. disclose a yeast three-hybrid assay using Dexamethasone-Methotrexate (see Figure 1 of the reference). Lin et al. disclose forming a screening molecule by covalently bonding said molecule to a substrate capable of selectively binding to and selectively forming a covalent bond with a receptor (see Figure 1 and page 4248 of the reference). Although Lin et al. does not explicitly teach a covalent bond, said bond is an inherent property based on the disclosure. In addition, Lin et al. disclose introducing the screening molecule into a cell culture comprising cells that express a first fusion protein of a DNA-binding domain fused to a target receptor domain against which the target molecule is screened (see Figs 1 and 2; and Table 1 of the

reference). Lin et al. also disclose a second fusion protein that comprises a receptor domain capable of binding to and forming a covalent bond with the screening molecule (see Fig. 1). Lin et al. disclose a reporter gene wherein expression of the reporter gene is conditioned on the proximity of the first fusion protein to the second fusion protein (see Fig 1). Finally Lin et al. disclose selecting the cells and identifying the target protein. Therefore, the limitations of the claims are met by the reference.

Conclusion

14. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

8/30/06

HOPE ROBINSON
PATENT EXAMINER

Application No.: 10/705,644

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [x] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other:

8. **Applicant Must Provide:**

- [x] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [x] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [x] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
- For CRF Submission Help, call (703) 308-4212
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